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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,169	07/13/2005	Edward A. Boyd	21242P	8248
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MERCK AND CO., INC			SHAMEEM, GOLAM M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,169

Applicant(s)

BOYD ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/15/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

This application is a 371 of PCT/US04/09028 03/24/2004 which claims benefit for domestic priority under 35 U.S.C. § 119(e) [to a provisional application 60/458,103 03/27/2003], is acknowledged.

Status of Claims

Claims 1-24 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on December 14, 2007 and that has been entered.

Claims 11-24 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 03/15/2007, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-10 drawn to a compound of the formula I and the elected species as set forth found in Example 41, with traverse is acknowledged. Applicant's arguments (to withdraw restriction among Groups 1-VI) are fully considered and found unpersuasive at this time because

the Invention groups I-VI differ materially in structure and in element from each other and therefore, are capable of supporting their own patents.

The invention Groups I-VI each relate to a set of structurally diverse and dissimilar compounds [having different variable groups, which are attached directly and indirectly to the formula I], process of preparing compounds, and their method of uses, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious. The core does not define a contribution over the art. The ring structure of formula I is further substituted by different variables such R¹, R², R³ and R⁴ etc, which are broadly defined and when the compound of formula I is taken as a whole, a plethora of vastly different compounds are possible. Thus, these features are not considered 'special technical features' under PCT rules 13.1 and 13.2. Hence, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In addition, 35 U.S.C. 372 (b)(2) clearly states that unity of invention may be reexamined under 35 U.S.C. 121. Restriction was based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B (2)(V) when dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the Examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. If the Examiner finds one of the inventions unpatentable over the prior art the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention. Nevertheless, Examiner may reconsider to rejoin one process of making claim and / or one method of use claim commensurate in scope with the product claims when the case would be found in condition for allowance [provided those process or method of use claims are free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, since 35 U.S.C. 101 allows one patent per invention, the requirement for restriction (election of species) is still deemed sound and proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

As set forth in the restriction requirement and an election of a single compound (or set of compounds), the scope of the invention which has been examined, inclusive of the elected species is as follows:

A compound of the formula I wherein:

R₁ is as claimed,

X is as claimed,

Y is as claimed,

Q is as claimed,

R₂ is claimed except "hydrogen, C₁₋₁₀ alkyl",

R₃ is limited to unsubstituted thiazolyl (heterocyclyl),

R₄ is as claimed,

R₅ is as claimed, and

R₆ is as claimed .

As a result of the election and the corresponding scope of the compound identified, claims 11-24 and the remaining subject matter of claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 11-24 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Pevarello *et al* (2000). Applicant claims substituted indole compounds, compositions and methods of uses thereof. Pevarello *et al* (2000) disclose the synthesis of several substituted indoles and their

derivatives and at least one of them anticipates the instantly claimed invention wherein R₁ is alkyl (Me), X is CH₂, Y is -CO, Q is N, R₂ is hydrogen, R₃ is substituted thiazolyl, R₄ is hydrogen, R₅ is alkoxy and R₆ is substituted aryl [STN International, HCAPLUS database, RN 267656-89-3 and a copy is provided with this Office action], which reads on the instantly claimed compounds.

Koo *et al* (2001) also disclose the synthesis of several substituted indoles and their derivatives and at least one of them anticipates the instantly claimed invention wherein R₁ is alkyl (Me), X is CH₂, Y is -CO, Q is O, R₂ is absent, R₃ is heterocyclyl (pyridinyl), R₄ is hydrogen, R₅ is alkoxy and R₆ is substituted aryl [STN International, HCAPLUS database, RN 80590-83-6 and a copy is provided with this Office action], which reads on the instantly claimed compounds.

Objections

Claims 1-10 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone

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number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

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